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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,314	03/14/2001	Randall W. Nelson	41821.0236	3078

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SNELL & WILMER L. L. P.  
ONE ARIZONA CENTER  
400 EAST VAN BUREN  
PHOENIX, AZ, 85004-0001

EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/808,314

Applicant(s)

NELSON ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 20-29, 31-33, 35-40, 42, 44-46 and 48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-33, 35-40, 42, 44-46 and 48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### Status of the claims

The amendment filed September 20, 2004 is acknowledged and has been entered.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 31-33, 35, 36-40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papac et al (Direct Analysis of Affinity-Bound analytes by MALDI/TOF, Anal. Chem. 1994, 66, 2609-2613) in view of Gaskell et al (Immunoabsorption to improve Gas chromatography/High-Resolution Mass spectrometry of estradiol-17B in Plasma).

Papac et al disclose a method for the Mass spectral identification and detection of analytes separated by immunoaffinity chromatography (abstract). Papac et al disclose antibody immobilized to agarose beads and used as affinity columns (p. 2611). Papac et al disclose combining a specimen with the beads to capture antigen present in the sample (post-combination affinity reagent). Papac et al disclose washing to remove any unbound antigen. Papac et al disclose that the sample is mixed with the beads and centrifuged and supernatant removed. Papac et al discloses that a matrix containing formic acid was added and the supernatant was tested by MALDI/TOF mass spectrometry (p. 2611, col 1 & p. 2613, col 2). Papac et al disclose determining the analyte by  $m/z$  (mass to charge ratio).

Papac et al (Anal Chem.) differ from the instant invention in failing to teach the specimen is combined with an internal reference species of known concentration prior to the capturing and isolation step wherein both the analyte and the IRS are captured and isolated.

Gaskell et al disclose the addition of an internal standard to a specimen containing analytes and determining the analyte by mass spectrometry. Gaskell et al disclose capturing and isolating the analyte and internal standard with an affinity

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reagent (solid phase antiserum). Gaskell et al disclose that a standard curve is used for the quantitation of the analyte and internal standard (p 678). Gaskell et al disclose that the standard curve was established by analysis of derivatized standard mixtures.

Gaskell et al disclose that the addition of the internal standard to the specimen provides higher precision to the analytical procedures (p. 677 & 679). Gaskell further discloses that the immunoabsorption technique provides a rapid and convenient procedure for an analyte before analysis (p. 679).

It would have been obvious to one of ordinary skill in the art to incorporate an internal standard and affinity reagents as taught by Gaskell et al into the method of Papac et al (Anal. Chem.) because Gaskell et al teaches that the addition of the internal standard to the specimen provides higher precision to the analytical procedures and also teaches that the immunoabsorption technique provides a rapid and convenient procedure for an analyte before analysis (p. 679).

5. Claims 44-46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papac et al (Anal. Chem.) and Gaskell et al in view of Merren (US 3,770,337).

See above for teachings of Papac et al and Gaskell et al.

Papac et al (Anal. Chem.) and Gaskell et al. differ from the instant invention in failing to specifically teach interpolating the analyte species mass spectrometric response to the IRS's mass spectrometric response.

Merren teaches the addition of reference substance which provides a spectrum containing peaks at several known mass-to-charge ratios. Merren teaches that the reference spectrum is accurately correlated with the spectrum of the unknown

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substance, therefore the reference peaks act as accurate markers forming a calibrated scale from which the mass-to-charge ratios of peaks of the unknown substance is interpolated. Merren teaches that this provides a method for combining signals representative of the simultaneous spectral analysis of two substances, thereby permitting single channel processing of the combined signal (col 1, lines 53 – col 2, lines 19).

It would have been obvious to one of ordinary skill in the art to interpolating the analyte species and the reference species as taught by Merren into the modified method of Papac et al (Anal. Chem.) because Merren shows that this provides a method for combining signals representative of the simultaneous spectral analysis of two substances, thereby permitting single channel processing of the combined signal.

### ***Double Patenting***

6. Claims 31 and 37 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-50 of copending Application No. 09/024,988. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the claims of application 09/808,314 do not require that the IRS is modified analyte with shifted molecule weight as independent claim 31 in application 09/024,988 one of ordinary skill would recognize that the claims of 09/024,988 would encompass claims of 09/808,314.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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***Response to Arguments***

7. Applicant's arguments with respect to claims 31-33, 35-40, 42, 44-46 and 48 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

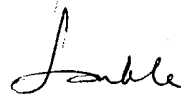
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
November 18, 2004



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

11/24/04